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MEMORANDUM

Date: April 28, 2009

Subject: Sulfur Dioxide. Review of Draft Study Protocol for Characterizing the Use of Sulfur Dioxide Pads on Blueberries.

PC Code: 111409

Decision No.: 406495

Petition No.: NA

Risk Assessment Type: NA

TXR No.: NA

MRID No.: None

DP Barcode No.: D362517

Registration No.: 56799PA1

Regulatory Action: Draft Protocol for New Use

Case No.: NA

CAS No.: 7681-57-4

40 CFR: §180.444

Ver. Apr. 08

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Executive Summary

Sulfur Dioxide (SO₂) is a commercial fumigant used for treating grapes and other fresh fruits as a fungicidal agent to control decay-causing organisms which induce spoilage. Permanent tolerances have been established under 40 CFR 180.444 for sulfite residues of the fungicide sulfur dioxide (determined as SO₂) in/on grapes, postharvest at 10 ppm. In support of the fresh fruit export industry, Productos Quimicos Y Alimenticios Osku S.A. (Osku) is a Chilean company in the forefront of producing SO₂ generating pads as packaging materials to protect grapes from decay. To further this use, Osku has worked to develop an extension of the SO₂ generator (Berry GuardsTM) to assist in the preservation of blueberries for export shipment and cold storage. To gain United States introduction, Osku has now submitted for review a draft study protocol for characterizing the use of their sulfur dioxide pads on blueberries.

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This project is designed to be a direct collaboration between Osku and the University of California, Davis to develop a database for the registration of this new fungicide use on blueberries, postharvest. Testing of the Osku Berry GuardsTM will be made to characterize both the single-box and pallet-size wrap type strip generator end use products. It will include validating product efficacy, determining sulfite residue levels in/on blueberries incurred through its use, and corrosion testing to assess overall generator stability. The Osku Berry GuardsTM are designed to be simple in-package single phase pads which allow for the slow and controlled release of SO₂ to occur inside a box of freshly harvested berries. Using sodium metabisulfite (Na₂S₂O₅) as its active ingredient, the moisture present in the refrigerated fruit boxes diffuses into the pad to produce SO₂ for controlling the emergence of fungal organisms. This experimental protocol for product testing is therefore intended to simulate the actual use of the Osku SO₂ generator pads in postharvest applications to blueberries using standard commercial practices.

Conclusions/Recommendations

To provide sufficient data for facilitating the registration of this new sulfur dioxide fungicide use, the registrant has provided a carefully planned and detailed product testing protocol. In general, it appropriately delineates representative numbers of samples for collection, handling requirements, and proper test procedures for each of the experiments to be performed. As such, the protocol provided by Osku is thorough in its approach including both data analysis and reporting requirements necessary for assessing the project objectives of this study. Although a practical experimental program is put forward with this protocol, there are additional criteria which should be included in the characterization of sulfur dioxide postharvest applications to blueberries. In carrying out this testing program it would be prudent for Osku to consider the following comments/recommendations in the development of their final protocol:

1. To ensure the quality and integrity of this data, the characterization of this new use shall be conducted in line with the Good Laboratory Practice (GLP) standards specified in 40 CFR Part 160. Likewise, any planned changes to the study protocol or unexpected deviations must be appropriately documented.
2. The description of the planned Berry GuardsTM product labeling must include an ingredient statement and directions for use as per 40 CFR Part 156, Subpart A. If it is not feasible to fit the entire label on the product container/wrapper, supplemental booklets or pull off labeling should be provided.
3. A key assumption is that the Berry GuardsTM will be used following SO₂ closed chamber fumigation to augment commercial shipping and cold storage practices. In accordance, this should be a requirement for use specified on the product label or at a minimum noted that for best results fumigate produce prior to its use.
4. Accelerated corrosion characteristics testing of the Berry GuardsTM is being proposed in the study protocol subject to Agency approval of the experimental method and data interpretation criterion. There is no foreseen objection to accelerated product corrosion testing provided that any such program initiated by the registrant is properly documented in this protocol or supplemental plan for assessment. This includes but is not limited to denoting the experimental conditions, whether it will be conducted using both end use products, number of samples, handling requirements, test methods, and data analysis/reporting criteria.
5. For the determination of SO₂ residues in/on blueberries, the optimized Monier-Williams method is specified for carrying out these analyses. To ensure this analytical protocol performs adequately, concurrent method recovery samples bracketing the anticipated concentration range of the sample results should be analyzed.

6. For this evaluation of postharvest applications to blueberries, the SO₂ generator pad results should be a similar in details to that which was acquired to support their use on grapes.

Provided that the comments/recommendations mentioned above are addressed, the submitted protocol is adequate. Following the outcome of this study, it is anticipated that the resulting label information will provide a similar level of product details for blueberries as now exists for grapes. This should include listing specifications for the pad size of each end use product (single-box & pallet-size), usage based on produce box weights, the weight of active ingredient per pad, and an ingredients statement.



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